

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX

Petitioner

File No. 86640-001

v

Assurity Life Insurance Company
Respondent

Issued and entered
this 1st day of February 2008
by Ken Ross
Acting Commissioner

ORDER

I

PROCEDURAL BACKGROUND

On December 10, 2007, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the request and accepted it for external review on December 17, 2007.

The Commissioner notified Assurity Life Insurance Company of the external review and requested the information used in making its adverse determination.

The case involves medical issues so the Commissioner assigned it to an independent review organization (IRO) which provided its recommendation to the Commissioner on December 31, 2007.

II

FACTUAL BACKGROUND

The Petitioner has group health care coverage with Assurity. The Petitioner was diagnosed

with metastatic melanoma which spread to her lungs. Her oncologist referred her to Dr. XXXXX at the University of XXXXX Hospital. After consultation with Dr. XXXXX, the Petitioner elected to participate in a Phase II Study of the drug AZD2171 (Recentin). By participating in the study, Petitioner received Recentin without cost to her or her insurer. The study did require, as a condition of participation, that needed lab work and CT scans be paid by the participant's insurer. Petitioner submitted claims for these items to Assurity. The bills for the tests conducted between April 5 and September 25, 2007 totaled \$7,754.00.

Assurity denied coverage asserting that the Petitioner is in a clinical trial which is experimental/investigative and is excluded in the Petitioner's policy. The Petitioner appealed but Assurity maintained its denial in letters to the Petitioner dated November 6 and November 30, 2007. (Neither of these letters is designated as a final adverse determination and neither meets the requirements for final adverse determination letters as set forth in section 7 of the PRIRA. (MCL 550.1907). However, it does appear that Respondent's letters constitute Respondent's final decision regarding Petitioner's claims and, for that reason, a PRIRA external review by the Commissioner is appropriate.

III ISSUE

Is Assurity Life required to provide coverage for Petitioner's tests and CT scans while she is participating in the AZD2171 clinical study?

IV ANALYSIS

Petitioner's Argument

The Petitioner says that during the clinical trials her tumors shrunk and eventually disappeared. The Petitioner says if she was not on this trial, the labs and scans to monitor her disease progression would be covered as routine costs. The Petitioner states she was removed from the trial because she does not have insurance coverage.

The Petitioner believes that Assurity should approve coverage for the past and future routine tests and procedures associated with the delivery of care for her cancer so that she can participate in the trial again.

Assurity Life Insurance Company's Argument

In its final adverse determination, Assurity says it was correct in denying coverage because for a treatment to be covered it must meet the policy's "Medical Care Necessity" standard:

"Medical Care Necessity" means that service or treatment, in order to be covered, must be considered necessary for the diagnosis or treatment of a Sickness or Injury, and must be given at the appropriate level of care.

- A) Services not considered necessary include, but shall not be limited to, the following:
 - a) Procedures of unproven value or of questionable current usefulness;
- * * *
- B) A service or treatment to be considered Medically Necessary must fulfill the following requirements:
 - (a) It must not be illegal.
 - (b) It must be safe and effective in treating the condition for which it is ordered.
 - (c) It must be part of a course of treatment which is generally accepted by the American medical community, including all branches of professional societies and governmental agencies.
 - (d) It must be of the proper quantity, frequency and duration for treatment of the condition for which it is ordered.
 - (e) It must not be redundant when it is combined with other services and supplies that are used to treat the condition for which it is ordered.
 - (f) It must not be Experimental/Investigative in nature.
 - (g) It must not be maintenance therapy or treatment.
- C) Assurity Life Insurance Company reserves the right to determine if a service or supply is Medically Necessary under the Policy(ies). This determination will consider, but will not be limited to, the findings and assessments of the following entities:
 - (a) The National Medical Association, Societies, and organizations.
 - (b) the Food and Drug Administration.

Assurity cited the Petitioner's consent for participation in the study which states in part: "the purpose of this study is to investigate an experimental agent, called AZD2171, which is not approved

by the FDA. . . . AZD2171 is an experimental drug If you participate in this study, some of these tests may be done more often than if you were not taking part in this study.”

Commissioner’s Review

The Commissioner has carefully reviewed the arguments of both parties as well as the documentation and certificate of group insurance. The Petitioner’s certificate of coverage lists its coverage exclusions and limitations including the following:

Unless otherwise specified under any benefit provision in the Policy, no payment will be made under the policy for expenses incurred by any Insured Person

* * *

- 18) for experimental procedures, treatment and surgery. Experimental procedures are defined as services, supplies, or treatment not recognized by the American Medical Association (AMA) or the U. S. Food and Drug Administration as an accepted medical practice necessary for the diagnosis or treatment of the condition of the patient. . . .

Because the case involves medical questions, Commissioner asked for the opinion of an IRO. The IRO reviewer discussed the typical care for an individual with Petitioner’s form of cancer:

Melanoma can spread by local extension (through lymphatics) and/or by hematogenous routes to distant sites. Any organ may be involved by metastases, but lungs and liver are common sites. Per the National Cancer Institute. . . “melanoma that has spread to distant sites is rarely curable with standard therapy. . . . All patients with distant metastasis are appropriately considered candidates for clinical trials exploring new forms of treatment. . . .

The National Comprehensive Cancer Network NCCN 2007 melanoma Treatment Guidelines states that the preferred treatment for metastatic melanoma is participation in a Clinical Trial.

Metastatic melanoma is associated with a poor prognosis. Several chemotherapeutic agents have shown activity in patients with metastatic melanoma. . . .However, little consensus currently exists regarding standard therapy.

The reviewer concluded that the Phase II clinical trial of AZD2171 for the treatment of metastatic melanoma is experimental/investigational and recommended, for that reason, that Assurity’s decision be upheld. The Commissioner accepts the IRO’s conclusion that the treatment is investigational.

Because the AZD2171 treatment is investigational, Respondent does not have to provide coverage for that treatment. However, AZD2171 treatment was not the medical service for which coverage was requested, so the analysis does not end there. Respondent sold the Petitioner a benefit plan that provides coverage for x-ray and laboratory charges. (See “Eligible Expenses” on page 32 of the Certificate.) The lab charges for which Petitioner seeks reimbursement are not, themselves, experimental. Respondent would have to provide coverage for such expenses in the course of any other non-investigational cancer treatment. As it is, the clinical trial treatment itself is being paid for by the trial sponsors, not Respondent. The Petitioner’s participation in the trial should not be used as a reason to avoid providing coverage for tests that Respondent would otherwise have to cover. This is particularly true where the Petitioner’s medical condition is not likely to respond to conventional treatment and where, as the IRO notes, the most reasonable decision for Petitioner was to enter a clinical trial.

The Commissioner notes that the Petitioner’s consent for participation in the study included the statement “If you participate in this study, some of these tests may be done more often than if you were not taking part in this study”. However, in its denial Assurity never included as a reason for denying coverage the frequency of the laboratory and x-ray services, as compared to lab and x-ray services related to standard treatment for melanoma that has metastasized. Denial or limitation for payment of these services due to the frequency they were performed was therefore not considered in the Commissioner’s review.

V ORDER

The Commissioner overturns Assurity Life Insurance Company’s adverse determination of November 30, 2007. Assurity Life is required to provide, within sixty days, coverage for Petitioner’s laboratory and other tests, subject to any applicable co-pays and deductibles. Assurity Life shall, within seven days of providing coverage, provide the Commissioner proof it has implemented the Commissioner’s Order. To enforce this Order, the Petitioner must report any complaint regarding

the implementation of this Order to the Office of Financial and Insurance Services, Health Plans Division, toll free 877-999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, P. O. Box 30220, Lansing, MI 48909-7720.